ASB Std 123, Standard for Routine Internal Evaluation of a Laboratory's DNA Interpretation and Comparison Protocol
24-May-21

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
30	Foreward	E	Comma needed between words 'Currently' and 'external'.	insert necessary comma	Accept.
1	General	T/E	The foreword of the document goes into great detail to explain the deficiencies of the proficiency-testing program that exists in many laboratories. However, this document does not provide enough information on how to execute this protocol. Adequate steps need to be taken to make this a blinded process where analysts don't know that they are being tested. Additionally, technical leaders adopting this program need to account for the possibility of cognitive bias affecting interpretations.	The document needs to encourage labs to make this as blind of a process as possible. This could be added to section 4.3 or 4.4 of the document. A CSAFE reference on implementing a blind proficiency-testing program can be added to the bibliography as well. In building this program technical leaders also need to account for ways cognitive bias could affect the results. Consider adding a bullet 4.4.3 requiring the technical leader to anticipate and attempt to mitigate steps in the testing process that could lead to biased testing program or interpretations (e.g. the naming of data, how analysts access data, ensuring a tested person and reviewer are not taking the same test, attempts to keep data from similar tests off of the same runs, etc.)	Reject. While that is a great idea, it is not reasonable based on how the test is set up with the goal for all analysts to work with the same DNA profiles. We encourage labs to try and implement blind testing, if possible. Bias is being considered in the set-up of the test, so no change is necessary.
38	general	T	This standard presents as an expansion beyond the annual TL case file review required by QAS 2020 updates, which targets review of reported casework vs this consensus study of interpretations of mock casework. There are already standards in place for SOP verification as part of the ASB validation standards for mixture verification, requiring mock cases independent of validation cases. The annual review in addition to annual proficiency testing requirements are mandatory for a lab to maintain accreditation; additional internal testing requirements beyond QAS may become burdensome to maintain compliance.	Consider shifting this to a best practice recommendation instead of a standard requirement.	Reject. It is critical to test difficult mixture sample interpretation and a standard is the best way to achieve this. It is up to the individual laboratory to implement this standard, since the implementation is voluntary.
15	throughout	T	this document is better written as a best practices document rather than a standard. Labs have ample opportunity to scrutinize their protocols without this formal process. Regular meetings, technical talks (how would you interpret this mixture), and literature reviews can all improve a lab's protocols. A lab performing this kind of annual review may benefit from it; however, a lab with a detailed protocol and open discussion is also a quality lab. The burden on a lab to implement this standard could be immense, especially to have a fullsome, almost validation-like yearly requirement. Labs finding other ways to scrutinize their protocols should not have to also comply with this.	change to a best practices document - the goal here is to ensure that the protocol is effective and applied uniformly. This can be evaluated in many different ways, and this standard describes only one of those ways. Standards should be reserved for requirements that, when they are not met, are detrimental to the quality of the work of the laboratory.	Reject. See comment #38.
35		T	We feel this entire document is excessive. Many labs already have policies, procedures, checks and balances, including technical reviews, in place to ensure consistency of interpretation and comparison amongst analysts. An additional standard should not be necessary, and could be a time consuming burden, especially for larger laboratories.		Reject. See comment #38.
2	1	T		Consider clarifying what is meant by "other test methods" in the first sentence of the second paragraph of the scope. Does this mean completely different platforms like NGS or different analysis methods that use CE like mitochondrial DNA and paternity testing? If a laboratory is routinely performing mitochondrial DNA or paternity testing, this protocol should apply there as well.	Accept. See paragraph 4 in the foreword for more specifics. Added "DNA testing" to sentence in Scope.

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10	1	E	Laboratories are already required to review protocols, train their analysts and evaluate the efficiency of a protocol prior to issuance.This could result in a significant burden to a laboratory to duplicate efforts that are already being performed in other ways. I do agree that this type of practice could be extremely beneficial when training new analysts and could be implemented in that manor. New analysts are already required to complete interpretation tests at the conclusion of their training and this requirement could be incorporated to verify their knowledge and ability to follow the protocol.	Make this a best practices or recommended document.	Reject. The goal is to monitor the continued and periodic assessment of case working analysts once interpretation training is completed. This is not intended to be a part of the training program.
3	2	E		In order to evaluate an interpretation and comparison protocol, having a preexisting protocol in place seems mandatory. At minimum ASB 40 should be considered as a normative reference for this document. There's an argument that can be made for the FBI QAS and the ISO 17025 being listed as normative, but we don't see how there are no normative references for this document.	Reject. All that is required is for the laboratory to have a protocol for interpretation and comparison of data. This is a stand alone standard that does not require a laboratory to comply with any other standards to implement this standard.
28	3.1	T	For the sake of clarity, it would be good to specify that the administrator cannot be the technical leader when the technical leader is participating in the internal evaluation.	Add the sentence, "When the technical leader is participating in the internal evaluation, another person must take on the Administrator role." to the end of the definition.	Accept with modification. The following text added to section 4.1.2: "When the technical leader is participating in the internal evaluation, another person shall take on the administrator role."
36	3.1	T	administrator defined as individual who oversees the evaluation, usually but not restricted to the TL. For purposes of QAS compliance, the TL should oversee the evaluation, and designate the administrator to conduct the evaluation (similar in nature to TL oversees quality program, training program, but designates quality manager/training management).	include in definitition that administrator will be designated by Technical Leader	Reject. Outside the scope of this document and addressed by individual laboratory policy.
4	3.2	T/E	The term data set is not defined in this document and only appears in this definition. A more definitive explanation of what is meant is needed. Is a data set unknown sample data from samples paired with references sample data or is unknown sample data a separate set from reference sample data? Lastly, is this annual test meant to have enough data sets that cover the range of casework samples per evaluation or does this mean that the sample variation changes over the life time of the program to capture the range of samples encountered in casework?	Data set should be defined in the document. An example of how this is versioned to be executed needs to be provided in the body of the document. Clarify if a data set for each evaluation covers the range of samples or if the overall program needs to cover the range of samples over time. An alternative word for data set, profiles, should be used in this definition since comparison is used in other documents and not in the contexts of data sets. Consider this change "the process of analyzing to or more DNA profiles to assess the degrees of concordance." Or "the process of analyzing two or more DNA testing results to assess whether a source or a contributor can be assigned."	Reject. This is the same definition used in ANSI/ASB Standard 040; it was kept the same for consistently. In addition, this standard applies to any type of DNA data, not just DNA profiles.
32	3.2	E	What is a "DNA data set?"	replace with "electropherograms or other instrument output"	Reject. This is dependent on the DNA methodology used and data being evaluated. See response to comment 4.
11	4.1	E	Reconsider the requirement for half of analysts complete this assessment due to some laboratories that have an odd number of analysts. If putting forth a requirement that a minimum of half of your analysts need to do this every year then with an odd number you would have one person repeating yearly and therefore would not be able to use the same samples. This creates an undue burden on laboratories to create and administer these tests.	Approximately half of qualified analysts	Accept. See note added under requirement 4.1.
12	4.1	E	How many "samples" would be required to complete this standard? 5, 10, 20?	Define minimal required number.	Reject. Requirement 4.2f has specific requirements for each individual lab to have flexibility depending on the complexity of mixtures that they typically encounter in casework. Similar language is used in validation standards to not include a minimum number of samples.

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13	4.1	E	If the technical leader is proficiency tested then they would be required to complete this assessement and therefore could not be an administrator. If the TL is proficiency tested, would they alternate yearly with an administrator? If the administrator is also a proficiency tested analyst and the "half of all analysts" remains a requirement then this goes back to laboratories with an odd number of analysts or smaller laboratories that would not be able to reuse samples year after year.	Define that if the TL is required to complete this requirement then an alternate administrator will evaluate the results. Approximately half of qualified analysts complete yearly or a randomized selection of analysts.	Accept. See added Note under 4.1 and second paragraph under 4.1.2.
16	4.1	T	if a technical leader is not PT'd, then they are exempt. If the TL is PT'd, they cannot both administer this evaluation and participate in it. Perhaps if the TL is the administrator, they can also be exempt from this requirement. Technical reviewers may not do independent interpretation, so may not need to be part of this evaluation either.	remove the list: "including analysts, technical reviewers, and the technical leader"	Reject. See second paragraph added under 4.1.2.
17	4.1	T	define annually	change first sentence: "...shall administer this internal evaluation program once per calendar year."	Reject. It is dependent on the laboratory's definition of annually.
18	4.1	T	define half: this is a balancing issue. The goal is to have everyone do it every other year, but people will leave and people will get trained. In a lab with 7 analysts, 3 will have it one year, and 4 the next. This is reasonable and allows a lab to use the same data set for two years before having to make a new data set.	Change "A minumum of half..." to "Approximately half..."	Accept with Modification. See added Note under 4.1
25	4.1	T	Can labs assign the analysts who completes the evaluation annually? And does that potentially skew the results?		Accept with Modification. See Note for Requirements 4.1 and second paragraph added under 4.2.1.
33	4.1	E	In "The laboratory shall administer this internal evaluation program annually." , what is "this" referring to?	The laboratory shall annually administer an internal evaluation of its DNA interpretation and comparison protocol	Reject. Style change only.
37	4.1	T	all staff must participate in the annual evaluation program every 2 years; half of the individuals qualified must participate every year, in addition to annual PTs. For large highthroughput labs, fluctuations in staffing numbers and qualifications in numerous amp kits may make this requirement difficult to satisfy. For example, a lab that uses multiple technologies (YSTRS, STRs, mtDNA) and multiple kits in each technology (4 kits in STRs, 2 kits in YSTRs).	allow flexibility to the laboratory to select representative participation to the extent individuals are routinely involved in casework across the extent of lab capabilities vs every user in every capacity.	Accept with modification. See new Requirements 4.1.1 and 4.1.2
19	4.1 NOTE	E	this note doesn't seem to belong here	move to 4.2.e as a second note, or incorporate it into the note already there	Reject. This is a note to suggest that single source samples that exhibit stochastic effects can be evaluated and analysts who only analyze single source samples can participate.
34	4.2	E	Somewhat confusing phrasing by starting subsections with "shall be" or "may be"	For clarity, each subsection should start with "The electronic data "	Accept with modification. "Shall be" and May be" were removed.
5	4.2a (now 4.2b)	T		Consider adding a note stating that data generated internally can be mixed with external data to create a data set.	Accept with modification. Added and/or.
26	4.2b (now 4.2c)	T	If validation data is used, and coded, can the original analyst who participated in the validation not participate in this evaluation?		Reject. The goal of this standard is to have independent evaluation of the data without the analyst having prior knowledge of the expected results.
14	4.2 b, c (now 4.2 c,d)	E	If making this a requirement, this could create an undue burden on laboratories that don't have validation support and/or complete their own validations while performing casework.	Make this a best practices or recommended document.	Reject. It is critical to test difficult mixture sample interpretation and a standard is the best way to achieve this. It is up to the individual laboratory to implement this standard, since the implementation is voluntary.
29	4.2c (now 4.2d)	T	This standard should encourage the use of data that can be released without privacy concerns whenever possible.	Add a sentence to 4.2c as suggested.	Reject. Outside the scope of this standard.

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20	4.2.e (now 4.2f)	T	this "representative" discussion is very broad. If this were a best practices document, perhaps there is a number that seems to work? As a standard document, less specificity here is better so labs can balance the work and rewards. Without the specificity, though, there is no guarantee that a lab will meet the spirit of this requirement. If there is a huge lab then this may work with fewer samples per analyst, but a small lab will be stuck with many samples per analyst. Still so much work to administer		Accept. No clear suggestion or resolution was provided. The commenter seems to be agreeing with 4.2 f as written.
6	4.2e (now 4.2f)	T/E		The use of “periodically” should be removed from 4.2.e. It is too vague. Periodically can be every five years. It would be better to just state that profiles exceeding the parameters and limitations of the laboratory protocol can be used in the evaluation than to provide an ambiguous time period that the lab cannot be audited against. Consider adding specific time periods for the use of these types of profiles, which is the better option, or remove “periodically.”	Accept with modification. Added that "where the period is defined by written laboratory protocol,"
7	4.2e (now 4.2f)	T		There are labs that utilize enhancement methods in their analysis. In addition to the sample types, the need for enhanced analytical instrument parameters needs to be captured in this section. Data sets should include original and enhanced runs when enhanced methods are used.	Accept with modification. See new Requirements 4.1.1 and 4.1.2.
27	4.2e (now 4.2f)	T	Clarification re: one ore more of the profiles exceeding the parameters and limitations of the laboroatory protocol should be included in the internal validation	For example, if off-scale data is used, is the goal that the analyst reject that sample if protocol dictates? Just trying to determine how this sample set should be created. Would samples with poor resolution also fit this criteria?	Accept. See new Requirements 4.1.1 and 4.1.2.
21	4.2.e (now 4.2f), 4.4, 4.4.1	E	the definitions of administrator and technical leader mean that perhaps TL can be removed in some of these places? Why note both?	replace technical leader/administrator with administrator throughout.	Accept.
31	4.4	E	Document routinely uses "technical leader / administrator". 4.4 uses "technical leader or administrator".	change "or" to "/"	Accept with modification. See Comment 21.
8	5	T/E		A summary of the results and outcomes from this testing should be included in the documentation.	Reject. 5.1 requires the details of each result and outcome of each of the participating personnel. This is duplicative.
22	5.1	T	the TL should be the approver. What "other appropriate personnel" would be the approvers?	remove "or other appropriate personnel"	Reject. See added section in 4.1.2 This also covers any supervisory personnel who do not have the title of technical leader.
9	5f (this should be 5.1.f)	T/E	Clarification is needed when addressing the role of the reviewer. Is this the person that performs the technical review of the exercise or is this the technical leader or assigned individual monitoring the entire program? As stated above, the potential for bias exists when a tech reviewer is taking the same test they are reviewing. Measures need to be taken to ensure that that does not happen. Therefore, there needs to be a cognitive bias statement within the document.	Clarify who is being described where it says, “who performed the review of the annual evaluation.” An acknowledgement of the potential for cognitive bias needs to be added to the standard.	Reject. See added section in 4.1.2. The reviewer of this internal evaluation is not a participant in the internal evaluation.
23	5.2	E	this list of possible actions is confusing to read, perhaps b/c of comma and semicolon placement	change to a bulleted list?	Reject. Use of semicolons is grammatically acceptable.
24	Annex A	E	"shall develop a list"; "shall be added to the laboratory's list" - there shouldn't be requirements listed in the annex. If these are requirements, they need to be added to the requirements section. Otherwise, change to should.	change "shall" to "should"	Accept with modification, shall statements removed per new ASB Manual